DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 2006D–0480]

Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration." In recent years, the practice of complementary and alternative medicine (CAM) has increased in the United States, and we have seen increased confusion as to whether certain products used in CAM are subject to regulation under the Federal Food, Drug, and Cosmetic Act (the act) or Public Health Service Act (PHS Act). We have also seen an increase in the number of CAM products imported into the United States. Therefore, the draft guidance discusses when a CAM product is subject to the act or the PHS Act.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug

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Administration, 1401 Rockville Pike, suite 200N Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0587.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration." The term "complementary and alternative medicine" (CAM) encompasses a wide array of health care practices, products, and therapies that are distinct from practices, products, and therapies used in "conventional" or "allopathic" medicine.

In the United States, the practice of CAM has risen dramatically in recent years. In 1992, Congress established the Office of Unconventional Therapies, which later became the Office of Alternative Medicine (OAM), to explore "unconventional medical practices." In 1998, OAM became the National Center for Complementary and Alternative Medicine (NCCAM). NCCAM is a center within the National Institutes of Health. The Institute of Medicine, in its book entitled, *Complementary and Alternative Medicine in the United States*, stated that more than one-third of American adults reported using some

form of CAM and that visits to CAM providers each year exceed those to primary care physicians (see Institute of Medicine, *Complementary and Alternative Medicine in the United States*, pages 34 through 35 (2005)).

As the practice of CAM has increased in the United States, we have seen increased confusion as to whether certain products used in CAM (which, for convenience, we will refer to as "CAM products") are subject to regulation under the act or the PHS Act. We have also seen an increase in the number of CAM products imported into the United States. Therefore, the draft guidance discusses when a CAM product is subject to the act or the PHS Act. (When the draft guidance mentions a particular CAM therapy, practice, or product, it does so in order to provide background information or to serve as an example or illustration; any mention of a particular CAM therapy, practice, or product should not be construed as expressing FDA's support for or endorsement of that particular CAM therapy, practice, or product or, unless specified otherwise, as an agency determination that a particular product is safe and effective for its intended uses or is safe for use.) The draft guidance makes the following two fundamental points:

- First, depending on the CAM therapy or practice, a product used in a CAM therapy or practice may be subject to regulation as a biological product, cosmetic, drug, device, or food (including food additives and dietary supplements) under the act or the PHS Act.

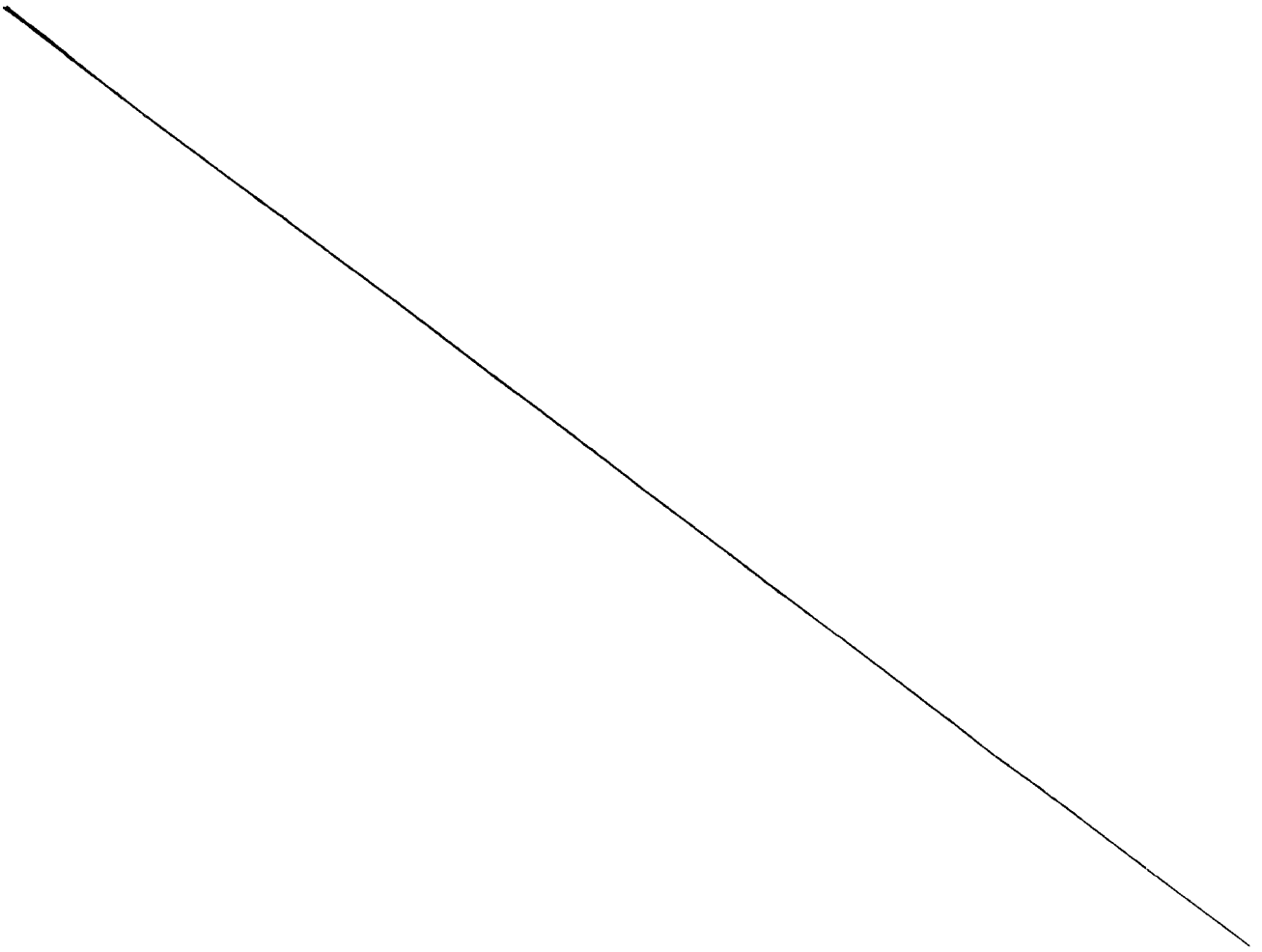
- Second, neither the act nor the PHS Act exempts CAM products from regulation.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the regulation of complementary

and alternative medicine products by FDA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: 12/6/06

December 6, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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